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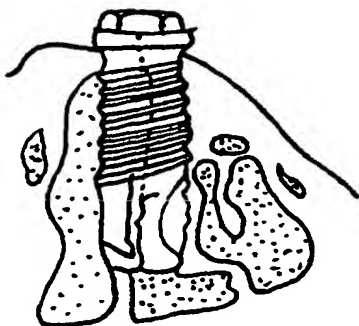
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(54) Title: AN ELEMENT INTENDED TO BE IMPLANTED IN BODY TISSUE, AND A DEVICE FOR MANUFACTURING SUCH AN ELEMENT



(57) Abstract: The invention relates to an element (1) intended to be implanted in body tissue, especially bone tissue (3), which exhibits a controlled surface structure on at least that part (4A) of the implant (1) which is so arranged as to be in contact with bone. Both the surface and the form of that part (4A) of the implant (1) that is so arranged as to be in contact with bone (3) are produced in a common operation, so that the surface exhibits controlled isotropic surface topography, which gives high repeatability. The invention also relates to a method for the production of elements and an arrangement for that purpose.

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5 An element intended to be implanted in body tissue, and a
device for manufacturing such an element

The present invention relates to an element intended to be implanted in body tissue, especially bone tissue, which exhibits a controlled surface structure on at least that part of the implant which is so arranged as to be in contact with bone.

Previously disclosed is the fact that the surface topography of an implant surface is of significance to how well it is integrated with surrounding tissues. For example, Wennerberg et al have described how the surface topography influences the healing process for implants in bone; ref. Wennerberg, PhD Thesis 1996, and Wennerberg, 1998 "A histomorphometric evaluation of screw-shaped implants each prepared with two surface roughnesses".

20 All implants available on the market exhibit more or less stochastic surface structures, which are the result of, for example, turning processes, milling processes, etching or blasting processes. These processes, among others, or combinations of them are used to control the topography of the surfaces. For example, Patent Application SE 7902035-0 describes an implant surface which is characterized by the fact that at least the surface layer consists of a material containing titanium, and that the surface is micro-pitted in the range from 10-1000 nm, and preferably 10-300 nm. The results are good for the surface, which is explained by the fact that the pits are of the same order of magnitude as the cells in the surrounding tissue.

Research shows that it is desirable to be able to control the surface structure better than is the case in conjunction with the use of the aforementioned traditional

methods for producing surfaces with different surface roughness. It is highly likely that surfaces with an even more controlled structure may be desirable in order further to improve and accelerate the integration of an implant in the surrounding tissue. Research is being conducted into, among other things, surfaces with a higher degree of control. These are generally referred to as micro-fabricated surfaces. Tools commonly used in the production of these surfaces include laser machining, or so-called laser ablation, whereby the surface layer is vaporized in a specific pattern either by positioning the laser and causing pits to be burnt at given distances, or by causing various optical arrangements to burn a particular pattern into the surface.

Other previously disclosed methods include the so-called lithographic methods (photo lithography and electro lithography) and special variants of these, for example so-called stamping, by means of which a pattern can be obtained with more control over the detail. Details which can be controlled are the distribution of patterns over surfaces and the depth of the pattern. These methods very often use some form of etching technology (wet, dry or electrochemical).

The advantage of the lithographic methods is that production can be made rather more rational than with the methods based on laser machining. When using laser methods, the laser beam must be repositioned between each stage of the machining process, whereas the lithographic methods can produce patterns over larger components at each machining stage.

A surface which is the result of laser machining is described in patent publication WO 95-09583. The pits in this case exhibit a mean diameter of 100-200 μm and can be likened to craters, since they are surrounded by raised areas which extend up above the surrounding implant surface and in this way form a border which fully or partially surrounds the pore.

One example shows that the pores have an average diameter of 150 μm and a depth of a similar order of magnitude. The crater contours are shown here to be raised by about 5 μm above the surrounding surface, and the average
5 distance between the pores is about 120 μm . Other previously disclosed methods for creating the desired surface roughness are blasting, etching or plasma spraying. Blasting is described in, for example, patent publications WO 92/05745 and WO 95/13102.

10 Patent EP 0 388 576 shows an implant surface produced by a combination of blasting and etching. The reason for the combination is to create a macrostructure with pores of the order of 10 μm in size with a superimposed microstructure with a pore size of 2 μm . It is stated in the
15 patent that the surface exhibits improved results in animal experiments.

An example of plasma-sprayed surfaces can be found in EP 0 222 853. The surface, which is the result of a plasma process, is a coarse and sponge-like structure.

20 Reference is also made to US-A-4,865,603, in which it is stated that "micro-texture is created by sequentially forming two sets of recesses in the outer surface of the prosthesis". In conjunction with this, it is stated that the purpose is to achieve a "readily controlled process" in order
25 to create the surface structure. Methods mentioned are "machine tooling, configured coating, laser metal removal and electrochemical", etc. This patent describes changes in the surface structure of the order of 300-700 μm , and the intention of these surfaces is to create mechanical locking
30 to the bone at macroscopic level, unlike the intention in the other patents referred to, where the surface structure is controlled on a significantly smaller scale with a view to accelerating the healing process and the formation of new bone. The intention is also for the implant to be used to
35 anchor joint prostheses, in the main hip prostheses. The

production methods that are used (blasting, etching and plasma spraying) are characterized by the fact that the resulting surface has an irregular topography which in itself exhibits a surface roughness which is repeatable if it is quantified by static surface roughness measurement methods (Rc, Sc values, etc.). On the other hand, the surfaces are not well controlled in such a way that the pattern can be clearly described at the level of micrometres and below, which is a precondition for optimizing the effect of the implant on the surrounding tissue. The sequence which leads to anchorage is determined by the interaction between the tissues and the surface of the implant during the healing phase. Mechanisms which control this interaction take place at molecular/protein/cell and tissue level. In order to be able to study the effect of the surface topography on the healing process more specifically, it is necessary to be able to control the structure of the surface in more detail. Attempts at this are described above with reference to laser machining and photo lithography. These methods are excellent if applied in a research context, although it is very difficult and expensive to reproduce the surfaces in large-scale production. The greater the control it is wished to have over the surface, the more complicated the production process becomes.

25 The principal object of the present invention is thus, in the first instance, to solve the aforementioned problems by simple means by the manufacture in a repeatable fashion of elements of the indicated kind, which exhibit surfaces with control at sub-micro level.

30 The aforementioned object is achieved by means of an element in accordance with the present invention, which is characterized essentially in that the surface and the form of that part of the implant that is so arranged as to be in contact with the bone are produced in a common operation, so

that the surface exhibits controlled isotropic surface topography with high repeatability.

The invention also relates to a method for the production of elements of the kind referred to above for the purpose of enabling the production in a repeatable fashion of elements of a kind which exhibit surfaces with control at sub-micro level to facilitate scaling-up the method to an industrial level and to increase the repeatability in relation to previously disclosed earlier methods which included laser ablation or lithographic methods, and now in a common operation.

A further object of the invention is thus to find a method which solves the aforementioned problems effectively.

The aforementioned further object is achieved by means of a method in accordance with the embodiment described above, which is characterized essentially in that both the surface and the form of that part of the implant that is arranged to be in contact with bone are produced in a common forming operation, so that the surface is given a controlled isotropic surface topography and with high repeatability.

Arrangements for the manufacture of implant elements of the kind intended in accordance with the invention have not made it possible to produce both the macrostructure and the microstructure of the element in a common production operation together with a controlled isotropic surface topography on the surface part of the element.

A final object of the invention is thus to provide means which satisfy the aforementioned wishes.

The aforementioned final object is achieved by means of an arrangement in accordance with the present invention, which is characterized essentially in that a tool for the manufacture of the elements in question exhibits a forming surface that is the reverse of the intended structure

of the element that it is intended to form, in respect of both its macrostructure and its microstructure.

The invention is described below as a number of preferred illustrative embodiments, in conjunction with which reference is made to the drawings, in which:

Fig. 1 shows an illustrative embodiment of an implant element which is provided with external threads;

Fig. 2 shows an example of an implant fixed in bone;

Fig. 3 shows the topography of a first example of a tool for the manufacture of elements and with a coarser surface;

Fig. 4 shows the topography of an element processed with a tool in accordance with the foregoing;

Fig. 5 shows the topography of a second example of a tool for the manufacture of elements and with a finer surface;

Fig. 6 shows the topography of an element processed with a tool in accordance with the second example.

The invention is described below as an example of implant elements 1 provided with threads 2 which are present for the purpose of increasing the fixing capability of the elements 1.

The invention can also be applied, however, to elements which lack threads, for example smooth, uniformly thick or conical fixing pins, etc.

Nevertheless, the following has emerged in respect of biological interest:

Increasing the surface roughness of screw-shaped implants from that obtained in conjunction with the turning of titanium has been found both to be associated with more rapid healing and to provide more bone in contact with the implant. This offers the possibility of shorter healing times, and thus shorter waiting times for the patients. Turned implants have a distinct orientation of their surface

structure (anisotropic), whereas blasted implants, for example, are isotropic. This characteristic can also provide an explanation for the increased amount of bone contact that is often observed in conjunction with implants with an
5 increased surface area. It is important to provide the surface of an implant with isotropic surface roughness in the area identified as optimal in previous studies, in such a way as to provide very high repeatability. Small changes can bring about a difference in the tissue response. That is why
10 repeatability is significant from the point of view of the prognosis.

Moreover, the manufacture of screws with the help of rolling has already been disclosed for some time, although providing the surface with a controlled isotropic topography
15 is novel. This method means that the thread profile of the screw and its surface topography are manufactured in a common operation. The surface topography of the tool results in a negative image on every unit manufactured. The method gives very high repeatability from batch to batch. An example of a
20 processing method used to obtain the macrostructure of the implant is thread-rolling or a similar method in which the thread profile is produced with plastic deformation and reproduction of the screw material in contact with the thread-rolling tool. The topography of the thread-rolling
25 tool that is reproduced in the surface of the screw can be manufactured by coating with the TopoCrom method, for example, Patent No. DE 334 122 C2, in which spherical peaks are reproduced as cavities in the surface of the screw, or by the use of equivalent technology, for example etching, in
30 which formed pits in the surface of the tool are reproduced as peaks in the surface of the screw, or by some other coating or machining process.

The screws that are manufactured are physically made with a standard thread with a pitch of 0.6 mm. The
35 microtopography is characterized by pits or peaks with peaks

and/or valleys with a height and/or a depth of 3-60 μm and a density of micropits and/or micropeaks of 50-5000/ mm^2 .

The invention is described more specifically as comprising an element 1, which consists of a titanium material or some other appropriately bone-compatible material with which to heal and fuse together, and which is intended to be implanted in body tissue, in particular bone tissue 3, such as the human jawbone in the case of a tooth implant or an implant for other odontological operations, which exhibits a controlled surface structure 4, 4¹ on at least that part of the implant 1 which is so arranged as to be in contact with bone. In accordance with the invention, both the surface 5, 5¹ and the form 9, 9¹ of the part 4A of the implant 1 which is so arranged as to be in contact with bone are manufactured in a common operation, so that the surface 5, 5¹ exhibits controlled isotropic surface topography. This provides high repeatability.

As stated above, it is preferably threads 2 which exhibit the aforementioned controlled isotropic surface topography 4, 4¹.

The surface 5, 5¹ of the aforementioned threads 2 or other parts of the implant 1 exhibits pits 6, 6¹ and/or peaks 7, 7¹, with peaks and/or valleys with a height and/or a depth of 3-60 μm and a density of micropits and/or micropeaks of 50-5000/ mm^2 .

A method for the production of such implant elements 1 proceeds in such a way that both the surface 5, 5¹ and the form 9, 9¹ of the part 4A of the implant 1 which is so arranged as to be in contact with bone are manufactured in a common forming operation, so that the surface 5, 5¹ of the manufactured implant 1 is given a controlled isotropic surface topography 4, 4¹ and with high repeatability.

In those cases in which the implant element 1 exhibits threads 2 or other suitable fixing devices and is executed as an implant screw, preferably made of a

homogeneous material or with a coating of a titanium material or some other bone-compatible material, the screw is manufactured so that both its macrostructure, i.e. its threads 2, and its microstructure, i.e. its specific and
5 desired surface structure, are produced in a common production operation and with a controlled isotropic surface topography in the threads 2, etc.

The thread profile of the screw is appropriately manufactured by thread rolling or by means of other
10 compression of the material in the screw 1 so that the thread profile is formed by plastic deformation and reproduction of the surface form 8, 8¹ of the thread-rolling tool or some other forming tool 10, 10¹.

The topography of the screw 1 is thus achieved by
15 reproducing an uneven but defined surface 8, 8¹ on the thread-rolling tool 10, 10¹ as the reverse of the form of the desired surface 5, 5¹, i.e. pits 11, 11¹ in the tool 10, 10¹ become peaks 7, 7¹ on the implant 1, and peaks 12, 12¹ in the tool 10, 10¹ become pits 6, 6¹ on the implant 1.

20 The problem of producing elements of the indicated kind in a repeatable fashion, which exhibit surfaces with control at the sub-micro level by a method that is readily capable of being scaled up to an industrial level is thus solved through the present invention. The repeatability also
25 increases in relation to the methods, which consist of laser ablation or lithographic methods.

Production thus takes place in a single stage with regard to both the macrostructure, e.g. threads, and the microstructure, the structure of the surface 5, 5¹ at μm
30 level.

The embodiment derives from the fact that both the macrostructure and the microstructure are created by pressing the surface to produce the desired structure. If the macrostructure is a thread, the production method can be
35 likened to thread-rolling, which is a production method

commonly used in the production of machine screws; for example, the roller jaws in this case can be provided, in addition to the form for the thread profile, with a surface structure at μm level. This structure produces an impression
5 in the surface in a highly repeatable fashion. Titanium, which is a familiar and well-documented material in implants, is an ideal material for production in this way.

One illustrative embodiment involves the use of thread-rolling, for which the roller jaws have been provided
10 with a surface layer containing the desired surface structure. One way of producing the surface structure is, for example, the commercially available, so-called Toppocrom method, in accordance with the above patent. This is marketed by WMV Angelagen AG, Germany, and is used in particular to
15 create a μ structure on rollers for sheet metalworking. The intention in many cases is to cause lubricant to bond to the surfaces. In addition to better repeatability, this method also gives a surface which is not chemically contaminated by chemicals that are used in the lithographic processes, for
20 example, or by the fact that chemical reactions are triggered by the heating that is unavoidable in conjunction with laser machining.

It is thus possible to utilize an applied surface coating on the thread-rolling tool in order, when it is
25 actuated, to obtain the desired impression on the implant 1.

An arrangement of the kind intended in accordance with the invention, which lends itself to use for the production of elements 1 intended for implantation in body tissue, in particular bone tissue 3, and which exhibits a
30 controlled surface structure on at least that part of the implant that is so arranged as to be in contact with bone, comprises a tool which is arranged for the manufacture of an element of the kind in question. The aforementioned tool 10,
10¹ exhibits a forming surface which is the reverse of the
35 intended structure, which is so arranged as to be formed on

the element 1 that it is intended to form, in respect of both its macrostructure and its microstructure.

As stated above, the tool may preferably be in the form of a press tool such as roller jaws, where the
5 macrostructure of the element includes threads 2.

The surface of the aforementioned tool 10, 10¹ exhibits an applied surface structure at μm level for the purpose of forming a controlled isotropic surface topography in the element 1 with high repeatability.

10 The invention thus provides for the simple and yet precise manufacture of implant elements 1, which exhibit the desired surface structure on all surfaces without problem. The invention is not, however, restricted to what is shown in the drawings and described above, but may be varied within
15 the scope of the Patent Claims without departing from the idea of invention.

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P a t e n t C l a i m s

- 5 1. Element (1) intended to be implanted in body tissue, especially bone tissue (3), which exhibits a controlled surface structure (4, 4¹) on at least that part of the implant (1) which is so arranged as to be in contact with bone, **characterized in that** the surface (4, 4¹) and the form
10 of that part of the implant (1) that is so arranged as to be in contact with bone are produced in a common operation, so that the surface (4, 4¹) exhibits controlled isotropic surface topography, which gives high repeatability.
2. Element in accordance with Patent Claim 1,
15 **characterized in that** it is threads (2) which exhibit the aforementioned controlled isotropic surface topography (4, 4¹).
3. Element in accordance with Patent Claim 2,
characterized in that the surface (5, 5¹) of the
20 aforementioned element (1) exhibits pits (6, 6¹) and/or peaks (7, 7¹), with peaks and/or valleys with a height and/or a depth of 3-60 μm and a density of micropits and/or micropeaks of 50-5000/ mm^2 .
4. Method for the production of an element (1)
25 intended to be implanted in body tissue, especially bone tissue (3), which exhibits a controlled surface structure (4, 4¹) on at least that part of the implant (1) which is so arranged as to be in contact with bone in accordance with one or other of Patent Claims 1-3, **characterized in that** both the
30 surface (5, 5¹) and the form (9, 9¹) of the part (4A) of the implant (1) which is so arranged as to be in contact with bone are manufactured in a common forming operation, so that the surface (5, 5¹) exhibits a controlled isotropic surface topography (4, 4¹) and with high repeatability.

5. Method in accordance with Patent Claim 4, in conjunction with which an element (1), which exhibits threads (2) or other fixing devices, is executed as an implant screw (1) preferably made of titanium material or some other bone-compatible material, *characterized in that* the screw (1) is manufactured so that both its macrostructure, i.e. its threads (2), and its microstructure, i.e. its surface structure, are produced in a common production operation and with a controlled isotropic surface topography in the threads (2).

6. Method in accordance with Patent Claim 5, *characterized in that* the thread profile of the screw is appropriately manufactured by thread rolling or by means of other compression of the material in the screw (1) so that the thread profile is formed by plastic deformation and reproduction of the surface form (8, 8¹) of the thread-rolling tool (10, 10¹).

7. Method in accordance with Patent Claim 6, *characterized in that* the topography of the screw (1) is achieved by reproducing an uneven but defined surface (8, 8¹) on the thread-rolling tool as the reverse impression, i.e. pits (11, 11¹) in the tool (10, 10¹) become peaks (7, 7¹) on the implant (1), and peaks (12, 12¹) in the tool (10, 10¹) become pits (6, 6¹) on the implant (1).

8. Method in accordance with Patent Claim 7, *characterized in that* an applied surface coating on the thread-rolling tool is used to obtain the reversed impression on the implant.

9. Arrangement for the manufacture of an element intended to be implanted in body tissue, especially bone tissue (3), which exhibits a controlled surface structure on at least that part (4A) of the implant (1) which is so arranged as to be in contact with bone in accordance with one or other of Patent Claims 1-3, *characterized in that* a tool (10, 10¹) for the manufacture of the element (1) in question

exhibits a forming surface (8, 8¹) that is the reverse of the intended structure (4, 4¹) of the element (1) that it is intended to form, in respect of both its macrostructure and its microstructure.

5 10. Arrangement in accordance with Patent Claim 9, *characterized in that* the tool is in the form of a press tool, such as roller jaws, where the macrostructure of the element includes threads (2).

11. Arrangement in accordance with Patent Claim 10,
10 *characterized in that* the surface of the aforementioned tool (10, 10¹) exhibits an applied surface structure at μm level for the purpose of forming a controlled isotropic surface topography on the element (1) with high repeatability.

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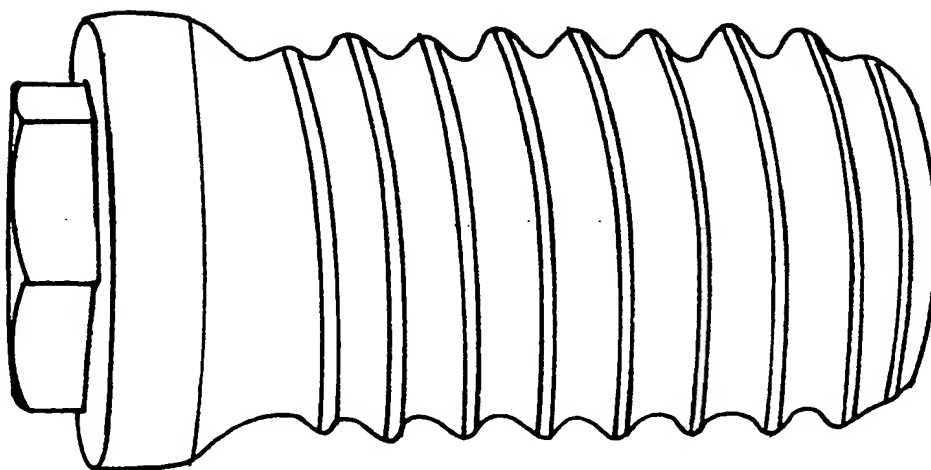


FIG. 1

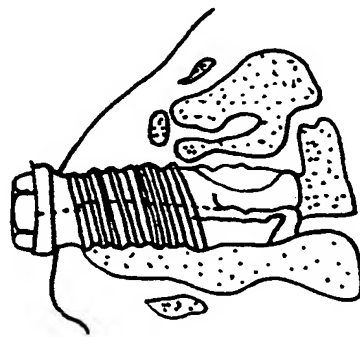


FIG. 2

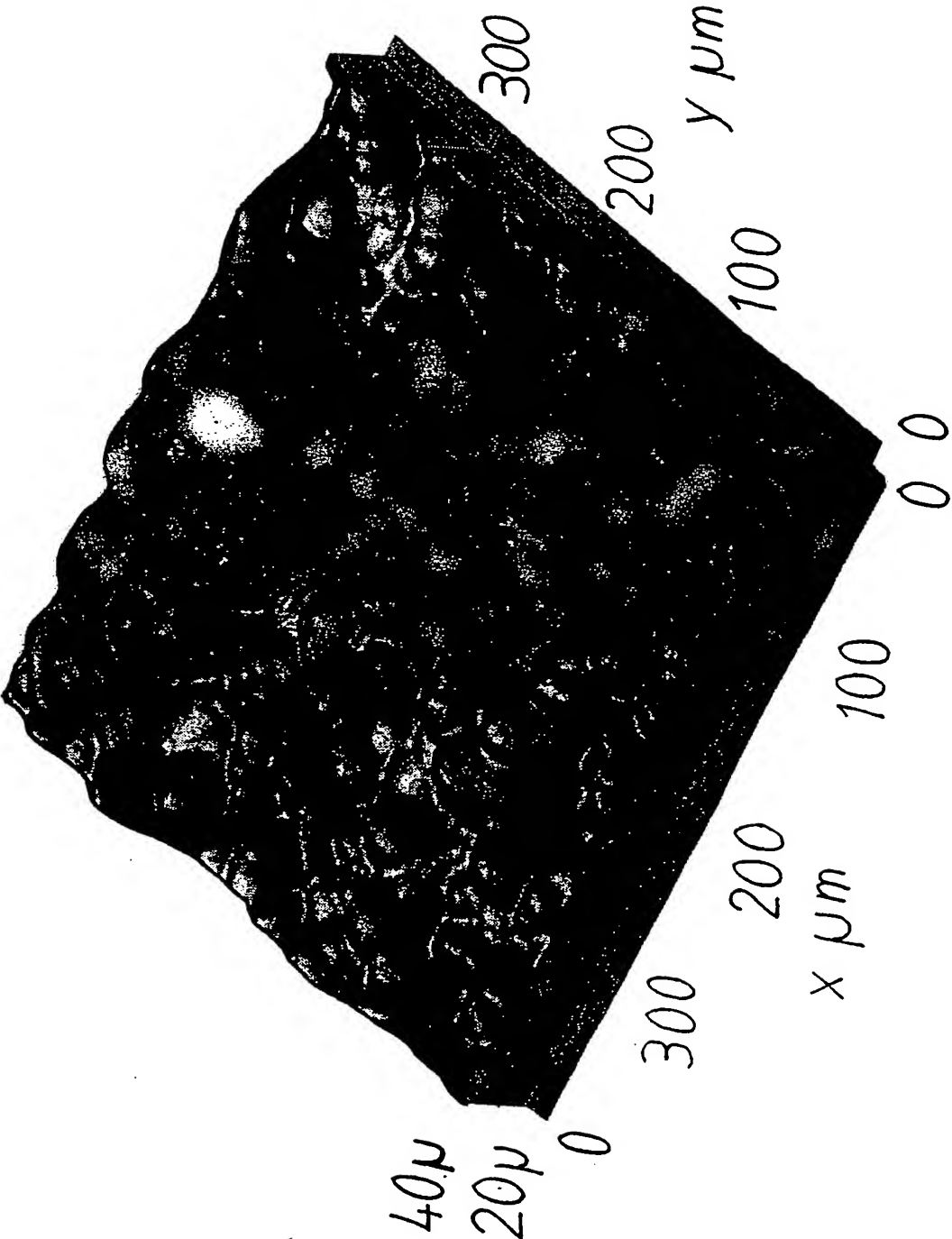


FIG. 3

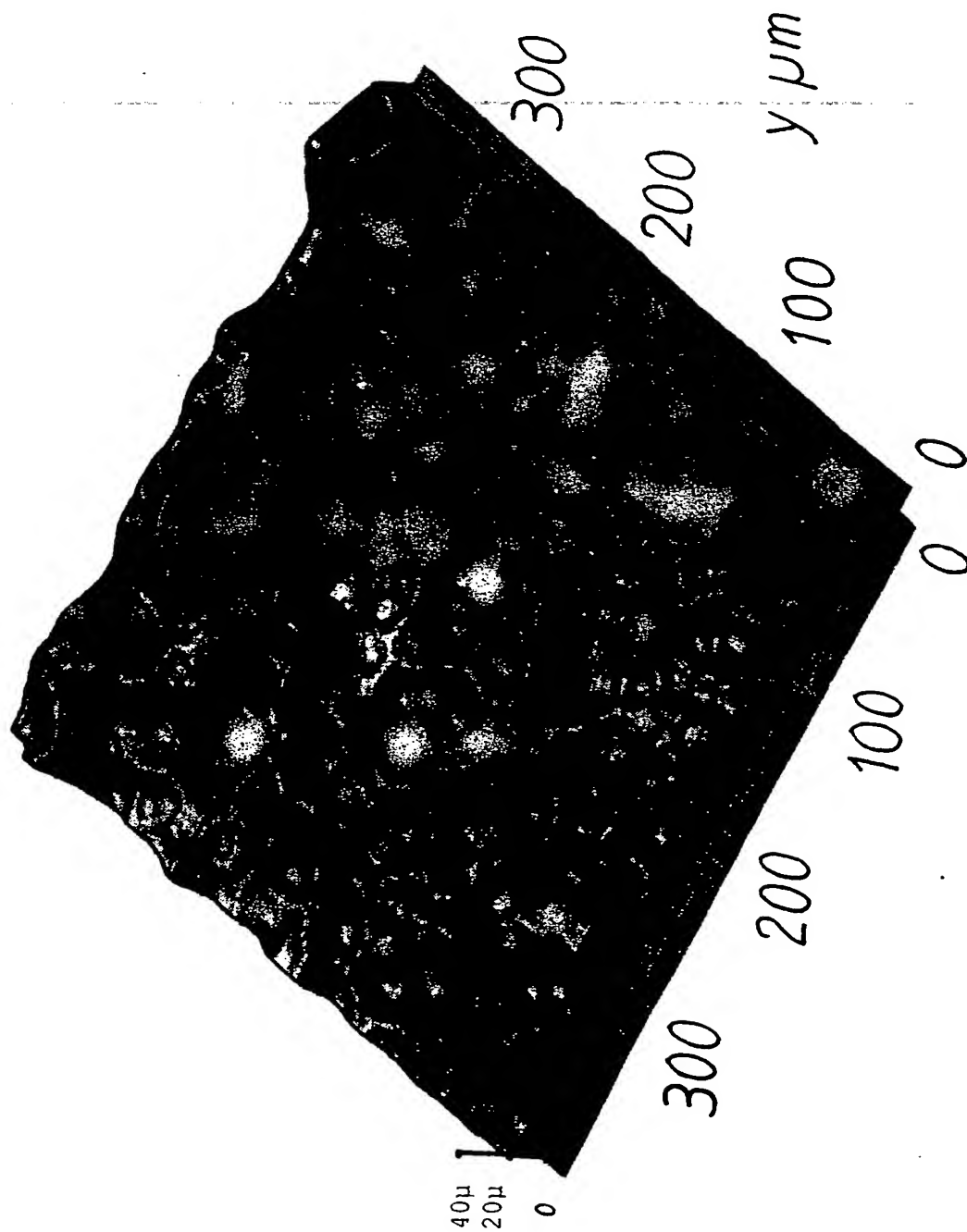


FIG.4

40μ
20μ
0

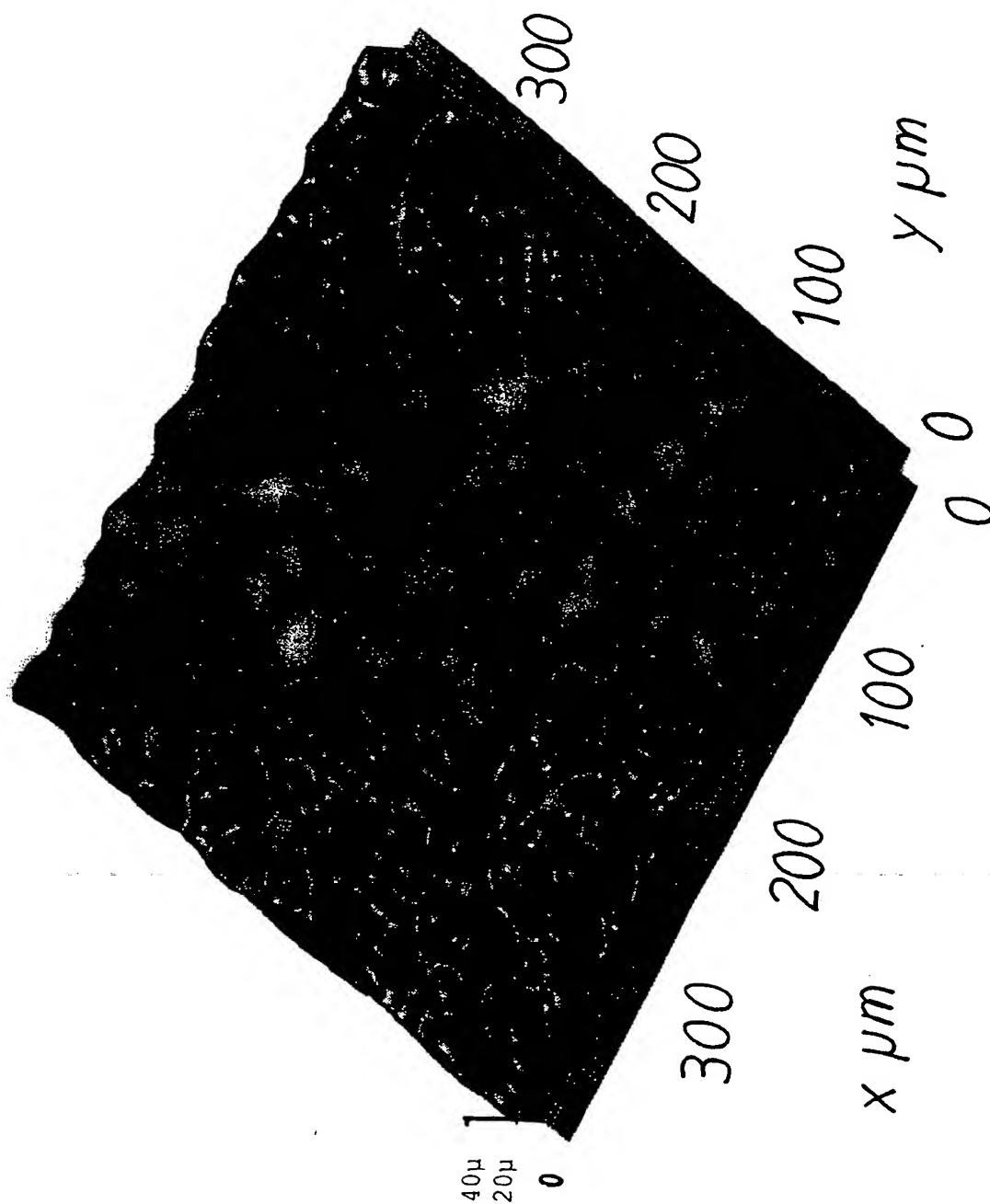


FIG. 5

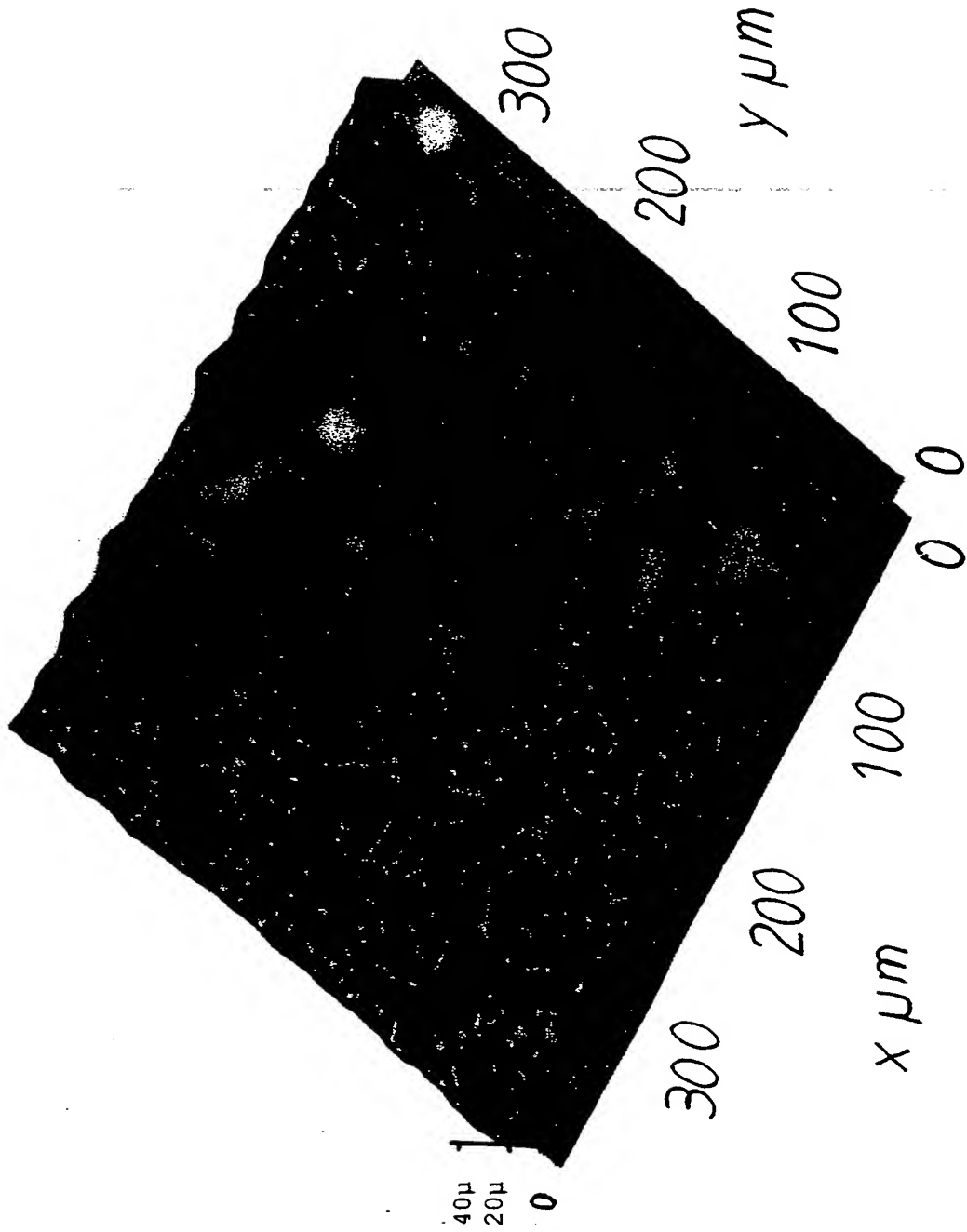


FIG. 6

INTERNATIONAL SEARCH REPORT

International application No.

PCT/SE 00/02171

A. CLASSIFICATION OF SUBJECT MATTER

IPC7: A61F 2/28, A61C 8/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC7: A61F, A61C

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	EP 0388576 A1 (INSTITUT STRAUMANN AG), 26 Sept 1990 (26.09.90) --	1-11
A	WO 9509583 A1 (LUCOCER AKTIEBOLAG), 13 April 1995 (13.04.95) --	1-11
A	WO 9513102 A1 (IMPLANT INNOVATIONS, INC), 18 May 1995 (18.05.95) -- -----	1-11

☐ Further documents are listed in the continuation of Box C.☒ See patent family annex.

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INTERNATIONAL SEARCH REPORT

Information on patent family members

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Patent document cited in search report				Publication date		Patent family member(s)	Publication date
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